In the United States Court of Federal Claims

No. 09-453V
(Filed Under Seal: October 12, 2023)
(Reissued for Publication: October 27, 2023)[1]

JEREMY HODGE, by his conservator ERIKA ELSON,	*
Petitioner,	*
v.	*
SECRETARY OF HEALTH AND HUMAN SERVICES,	*
Respondent.	*

Renée J. Gentry, Washington, DC, for petitioner.

Bridget A. Corridon, United States Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

SWEENEY, Senior Judge

Petitioner Erika Elson filed an amended petition under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34, alleging that her son's neurological issues were significantly aggravated by his hepatitis A and hepatitis B vaccinations. The special master determined that petitioner did not satisfy her burden of establishing entitlement to compensation. Petitioner moves for review of that decision, arguing that the special master improperly raised her burden of proof. As explained in more detail below, the court denies petitioner's motion.

[1] Vaccine Rule 18(b), included in Appendix B of the Rules of the United States Court of Federal Claims, affords each party fourteen days in which to object to the disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy." Neither party objected to the public disclosure of any information included in this opinion.

I. BACKGROUND

Unfortunately, this case has, for a number of reasons, spent an uncharacteristically long time in the Vaccine Program without a final resolution.[2] It is fair to say that no one involved in this case takes any pleasure from this fact. However, petitioner's motion for review is directed solely to the substance of the special master's most recent decision on entitlement. Consequently, the court will forgo a lengthy recitation of the case's procedural history and focus on the facts necessary to resolve the motion currently before it.

Jeremy Hodge was born on May 15, 1987.[3] His medical records reflect a number of normal childhood illnesses and injuries through July 8, 1996, when he was nine years old. There are no medical records from that date until March 10, 2004, when he visited a pediatrician. Notably, by September 28, 2004, when he was seventeen years old, Mr. Hodge began to exhibit symptoms of obsessive-compulsive disorder ("OCD").[4]

During a doctor's visit on March 17, 2006, Mr. Hodge received a hepatitis A vaccination and his first hepatitis B vaccination. He returned to the clinic on April 25, 2006. Among his complaints were uncontrollable eye movements, and the treating physician referred Mr. Hodge to a neurologist.[5] Mr. Hodge also received his second hepatitis B vaccination during this visit.

On June 2, 2006, Mr. Hodge was evaluated at an emergency room for balance issues, dizziness, eye movement disturbances, fatigue, and pain. The medical provider noted impressions of dizziness and arthralgias-myalgias following the hepatitis vaccination, and the diagnosis at discharge was neurological problems.[6] Six days later, at petitioner's request, one of

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[2] Those reasons are described in prior decisions in this case. See, e.g., Hodge v. Sec'y of HHS, 164 Fed. Cl. 633, 635-36 (2023) (setting forth a concise recitation of the case's procedural history); Hodge v. Sec'y of HHS, No. 09-453V, 2023 WL 4186513, at *1-10 (Fed. Cl. Spec. Mstr. May 24, 2023) (setting forth a fuller recounting of the case's procedural history).

[3] Unless otherwise noted, the facts are taken from the special master's decision. See generally Hodge, 2023 WL 4186513, at *14-42.

[4] The court made this fact finding in its prior decision, based on the preponderant evidence in the record. See Hodge, 164 Fed. Cl. at 647-48 (recounting the evidence in support of this fact finding).

[5] In her motion for review, petitioner twice asserts that the special master "failed to note" the referral to the neurologist. Mot. 3 n.3, 18 n.33. This assertion is incorrect; the special master references the referral several times in his decision. See Hodge, 2023 WL 4186513, at *41, *70, *72.

[6] In her motion for review, petitioner twice asserts that the special master "leaves out the diagnosis of 'Neurological Problems.'" Mot. 3 n.5, 19 n.35. This assertion is incorrect; the special master noted the diagnosis in his fact findings on the precise page identified by petitioner. See Hodge, 2023 WL 4186513, at *24.

Mr. Hodge's physicians agreed to request an MRI for Mr. Hodge. However, Mr. Hodge did not obtain an MRI at that time. In fact, Mr. Hodge did not undergo an MRI until May 19, 2009. The MRI revealed white matter hyperintensities in Mr. Hodge's brain, leading a neurologist to suggest the possibility of a demyelinating disease, among other potential diagnoses. A blood test on June 5, 2009, revealed the presence of antibodies for Borrelia burgdorferi, suggestive of Lyme disease, but subsequent testing for those antibodies had negative or inconclusive results. On December 11, 2009, an infectious disease specialist indicated that Mr. Hodge's symptoms were consistent with chronic neuroborreliosis. Preponderant record evidence reflects that Mr. Hodge was exposed to ticks and contracted Lyme disease before he began to exhibit symptoms of OCD in 2004.[7]

Mr. Hodge, in his individual capacity, filed a petition for compensation under the Vaccine Act on July 15, 2009, alleging unspecified injuries arising from his hepatitis A and hepatitis B vaccinations. His mother was subsequently appointed as his conservator and substituted as the petitioner in this case. Thereafter, on March 6, 2017, petitioner filed an amended petition to specify her son's injury: a significant aggravation of his preexisting neuroborreliosis.

Petitioner filed several expert reports from Carlo Tornatore, M.D., along with supporting medical literature. Dr. Tornatore posited that Mr. Hodge's chronic neuroborreliosis was aggravated by the hepatitis B vaccinations, which caused an autoimmune demyelinating event that manifested neurologically as abnormal eye movements. Dr. Tornatore acknowledged, however, that the May 2009 MRI showing demyelination did not establish that Mr. Hodge suffered from a demyelinating event in March or April 2006, and that none of Mr. Hodge's treating physicians in 2006 considered Mr. Hodge's symptoms to be a demyelinating event.

Respondent filed two expert reports and supporting medical literature from Arun Venkatesan, M.D., Ph.D., who disagreed with Dr. Tornatore's conclusion that the hepatitis B vaccinations administered to Mr. Hodge caused a demyelinating event. Petitioner and both experts testified during a two-day entitlement hearing, and the parties provided the special master with extensive written and oral argument on entitlement issues.

On September 12, 2022, the special master issued his initial entitlement decision. He concluded that petitioner had not established a necessary factual predicate for her theory of causation and therefore could not prove entitlement to compensation. Petitioner timely moved for review. In a March 7, 2023 decision, the undersigned granted the motion, set aside certain fact findings and legal conclusions made by the special master, made its own findings of fact, and remanded the case to the special master to reevaluate petitioner's entitlement to compensation.

The special master issued his decision on remand on May 24, 2023. The decision contains a comprehensive recounting of the factual evidence in the record—including Mr. Hodge's medical and school records, petitioner's affidavits, the expert reports, the medical

[7] The court made this fact finding in its prior decision. See Hodge, 164 Fed. Cl. at 648 (recounting the evidence in support of this fact finding).

literature, and the oral testimony elicited from petitioner and the experts during the entitlement hearing—and the parties' contentions. After considering the record evidence in light of the applicable legal standards, the special master concluded that petitioner did not satisfy her burden of establishing that Mr. Hodge's injuries were caused by his vaccinations. Petitioner timely moved for review, and respondent filed a response. Neither party requested oral argument and the court deems such argument unnecessary.

II. DISCUSSION

A. Standard of Review

The United States Court of Federal Claims ("Court of Federal Claims") has jurisdiction to review the record of the proceedings before a special master, and upon such review, may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
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> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
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> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The standards set forth in § 300aa-12(e)(2)(B) "vary in application as well as degree of deference. . . . Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." Munn v. Sec'y of HHS, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

Here, petitioner's sole enumerated objection to the special master's decision, articulated pursuant to Vaccine Rule 24(a), is that the special master improperly elevated her burden of proof "by explaining away or dismissing virtually every argument and piece of evidence offered in" her case.[8] Mot. 2, 10. This method of analysis, she argues, is "legal error." Id.; accord id. at

[8] In the "Relevant Caselaw" section of her motion, petitioner also contends that the special master "improperly reject[ed] her expert's testimony based on his 'demeanor' and 'credibility,'" Mot. 9, but she does not revisit this contention in her motion's legal argument section except in a footnote: "Throughout his decision, the Special Master paints Dr. Tornatore's testimony as lacking credibility due to his 'demeanor'. He has an entire breakout section on Dr. Tornatore's 'demeanor'. . . . He uses this 'demeanor' evaluation to give Dr. Tornatore's testimony less weight. Petitioner asserts this is also legal error." Mot. 16 n.30. Although the court need not entertain arguments raised in footnotes, see SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1320 (Fed. Cir. 2006), it observes that the special master's commentary on Dr. Tornatore's "demeanor" is limited to Dr. Tornatore's testimony regarding (1) a portion of the special master's significant aggravation analysis not being challenged by petitioner, see Hodge,

10 ("[T]he Special Master once again erroneously extracts each piece of evidence from the whole and rejects each one as not individually meeting the preponderance standard in a manner that is not in accordance with the law."). When faced with such a contention, the Court of Federal Claims reviews the special master's application of the law de novo. Rodriguez v. Sec'y of HHS, 632 F.3d 1381, 1384 (Fed. Cir. 2011).

B. Legal Standards

Petitioner's objection relates to the special master's determination that petitioner did not satisfy her burden of proving that the hepatitis B vaccinations Mr. Hodge received caused the significant aggravation of his preexisting neuroborreliosis. There is an established framework for assessing such claims:

> A petitioner must prove by preponderant evidence that the vaccination caused significant aggravation by showing:
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> > (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) . . . a proximate temporal relationship between the vaccination and the significant aggravation.

W.C. v. Sec'y of HHS, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (alteration in original) (quoting Loving v. Sec'y of HHS, 86 Fed. Cl. 135, 144 (2009)). These six factors are collectively referred to as the Loving test.

At issue in this case are the final three prongs of the Loving test, which "correspond to the three-part inquiry articulated in Althen v. Secretary of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005)." Sharpe v. Sec'y of HHS, 964 F.3d 1072, 1081 (Fed. Cir. 2020). Under Loving prong 4, a petitioner is "required to present a medically plausible theory demonstrating that a vaccine 'can' cause a significant worsening of" the condition at issue. Id. at 1083. To make this showing, "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Broekelschen v. Sec'y of HHS, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (quoting Knudsen v. Sec'y of HHS, 35 F.3d 543, 548-49 (Fed. Cir. 1994)). Loving prong 5 requires a petitioner "to show that the vaccinations 'did' cause a

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2023 WL 4186513, at *47-48 (discussing a part of the significant aggravation analysis for which the special master found in petitioner's favor), cited in Mot. 16 n.30; and (2) a single aspect of an ultimately nondispositive portion of the special master's significant aggravation analysis, see id. at *67 n.81. Consequently, assuming petitioner's contention were accurate, it would have no bearing on the outcome of her motion for review.

worsening of the" condition at issue. Sharpe, 964 F.3d at 1085. And, Loving prong 6 requires a petitioner to establish that the significant aggravation "occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan v. Sec'y of HHS, 539 F.3d 1347, 1352 (Fed. Cir. 2008). A failure to establish Loving prong 4—that the vaccination can cause the significant aggravation—or Loving prong 5—that the vaccination did cause the significant aggravation—is necessarily fatal to a petitioner's case.

Causation under the Vaccine Act can be established with circumstantial evidence—in other words, with medical records or medical opinion. Althen, 418 F.3d at 1279-80 (citing 42 U.S.C. § 300aa-13(a)(1)); see also Knudsen, 35 F.3d at 548 (observing that the "'logical sequence of cause and effect' must be supported by a sound and reliable medical or scientific explanation" (citing Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993); Jay v. Sec'y of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993))). A petitioner "need not produce medical literature or epidemiological evidence to establish causation," but "where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury." Andreu v. Sec'y of HHS, 569 F.3d 1367, 1379 (Fed. Cir. 2009). But see LaLonde v. Sec'y of HHS, 746 F.3d 1334, 1341 (Fed. Cir. 2014) ("In Vaccine Act cases, petitioners must proffer trustworthy testimony from experts who can find support for their theories in medical literature in order to show causation under the preponderance of the evidence standard. The level of specificity of such support may vary from circumstance to circumstance."). Moreover,

> to say that proof in the form of epidemiological studies or well-established medical experience is not mandatory does not mean that the special masters in Vaccine Act cases are precluded from inquiring into the reliability of testimony from expert witnesses. Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and . . . the special masters have that responsibility in Vaccine Act cases.

Moberly v. Sec'y of HHS, 592 F.3d 1315, 1325 (Fed. Cir. 2010).

Finally, as set forth in the Vaccine Act, when reaching a conclusion on causation, special masters must consider the record as a whole. 42 U.S.C. § 300aa-13(a)(1), (b)(1); accord Moriarty v. Sec'y of HHS, 844 F.3d 1322, 1330 (Fed. Cir. 2016). In doing so, they must ensure that they do not focus on individual pieces of evidence at the expense of determining what is depicted by the entirety of the record. See, e.g., Paluck v. Sec'y of HHS, 786 F.3d 1373, 1382-83 (Fed. Cir. 2015) (holding that "the special master failed in his duty to consider 'the record as a whole'" by "placing undue emphasis on the relatively insignificant variations" in some of a particular provider's records, thereby "giv[ing] short shrift to the evidence" of the child's condition reflected in the entirety of that provider's records); Snyder v. Sec'y of HHS, 553 F. App'x 994, 1000, 1003 (Fed. Cir. 2014) (unpublished decision) (concluding that the special master properly "examin[ed] the record in its entirety" when he found that the respondent's evidence showed that the children's seizure disorders were caused by a factor unrelated to the vaccine, observing that the special master "did the analysis necessary to decide the Secretary had

the stronger case based on testimony and the intellectual strength of the evidence, as well as the arguments presented"); Cedillo v. Sec'y of HHS, 617 F.3d 1328, 1345 (Fed. Cir. 2010) (approving the special master's separate evaluation of each piece of evidence, and remarking that "[i]n the Special Master's careful and thorough opinion, he considered, weighed, and stated his reasons for rejecting or discounting each item of evidence in which the petitioners relied"); Golub v. Sec'y of HHS, 243 F.3d 561 (Fed. Cir. 2000) (per curiam) (unpublished table decision) (criticizing the special master for "treat[ing] each element of the evidence individually, discrediting each piece of evidence in turn, without considering the totality of the evidence").

C. Loving Prong 4

The special master concluded that petitioner demonstrated Mr. Hodge's condition prior to the administration of the hepatitis B vaccinations (Loving prong 1); Mr. Hodge's current condition (Loving prong 2); and that Mr. Hodge's current condition is worse than it was prior to the vaccinations, in other words, that there was a significant aggravation of Mr. Hodge's condition (Loving prong 3). Because these conclusions were in her favor, petitioner understandably does not object to them. Rather, petitioner contends that the special master erroneously elevated her burden of proof with respect to the final three Loving prongs, primarily focusing on Loving prong 4.

With respect to that prong, petitioner argues that the special master's "primary error," Mot. 10, was that he "failed to consider the cumulative impact" of the evidence in the record in determining whether she had satisfied her burden of proof, id. at 17. In support of this argument, she contends that the special master conflated her theory of causation (that the hepatitis B vaccinations aggravated Mr. Hodge's existing neuroborreliosis and triggered "an immune response characterized by autoimmune inflammation that ultimately resulted in autoimmune demyelination") with the biological mechanism that was proposed to explain how the purported immune response could have been triggered ("molecular mimicry"). Id. at 11. Consequently, she asserts, "rather than view evidence regarding molecular mimicry as circumstantial evidence in support of the theory, [the special master] drew a bright line and found that [her] failure to prove the biological mechanism was failure to prove her theory of causation."[9] Id. at 17. Relatedly, petitioner also argues that the special master erred by "examin[ing] and dismiss[ing] every single article" she submitted as "insufficient," preventing her "use of circumstantial evidence in support of her case" and "instead requiring direct proof." Id. at 18.

It is undisputed that petitioner is not required to prove the specific biological mechanism leading to the significant aggravation of Mr. Hodge's injuries. Stone v. Sec'y of HHS, 676 F.3d

[9] Petitioner contends that the special master "did so by relying on the erroneous interpretation that Boatmon raised Petitioner's burden of proof by conflating biologically plausible theory with biological mechanism." Mot. 17 (citing Hodge, 2023 WL 4186513, at *53). Petitioner is incorrect. The special master did not cite Boatmon v. Secretary of HHS, 941 F.3d 1351 (Fed. Cir. 2019), as setting forth the applicable standard in this case. Rather, he referenced Boatmon when describing respondent's position on the applicable legal standard. Indeed, in the very next paragraph of his decision, the special master sets forth the correct legal standard, which is identical to the one propounded by petitioner.

1373, 1384 (Fed. Cir. 2012); Simanski v. Sec'y of HHS, 671 F.3d 1368, 1384 (Fed. Cir. 2012). Indeed,

> [i]t is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the . . . injury, as long as the petitioner can show by a preponderance of the evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be.

Simanski, 671 F.3d at 1384. Nor is it disputed that petitioner is entitled to rely on circumstantial evidence to establish that Mr. Hodge's injuries can be caused by the hepatitis B vaccination. See, e.g., Althen, 418 F.3d at 1279-80; Knudsen, 35 F.3d at 548. The special master correctly articulated petitioner's burden: He quoted the three-prong Althen test, recognized that all three prongs must be satisfied by a preponderance of the evidence, and reiterated the statement from Broekelschen that the first Althen prong—Loving prong 4—is satisfied with "a reputable medical or scientific explanation pertain[ing] specifically to the petitioner's case" that is "legally probable, not medically or scientifically certain." Hodge, 2023 WL 4186513, at *53 (quoting Bull v. Sec'y of HHS, 156 Fed. Cl. 329, 336 (2021)). And, as set forth below, there is no indication that the special master elevated that burden by requiring petitioner to definitively establish with direct proof that the hepatitis B vaccination can cause an autoimmune demyelination via molecular mimicry.

As explained by the special master, petitioner's expert, Dr. Tornatore, opined that neuroborreliosis is an autoimmune demyelinating disease, that the hepatitis B vaccinations triggered an autoimmune demyelination in Mr. Hodge that aggravated his underlying demyelinating disease, and that it was "biologically plausible for the hepatitis B vaccine to cause autoimmune demyelination" through a mechanism known as molecular mimicry. Id. at *56-59 (quoting Pet'r's Ex. 29 at 10); see also id. at *59-60 (recounting Dr. Tornatore's explanation that the antigens in the hepatitis B vaccine may share homology with myelin basic protein, and thus upon vaccination, antibodies are triggered that can cross-react against the hepatitis B virus and myelin). Consequently, the special master first evaluated whether petitioner had established that neuroborreliosis is an autoimmune demyelinating disease and then turned to the question of whether a hepatitis B vaccination could cause or aggravate an autoimmune demyelinating disease.

With respect to the first inquiry, the special master reviewed the opinions of Dr. Tornatore and respondent's expert, Dr. Venkatesan, along with two articles relied upon by Dr. Tornatore. He noted at the outset that the evidence was mixed. For example, he observed that in the Hildenbrand article, "autoimmune reaction via molecular mimicry" was listed as one "putative mechanism[]" for Lyme neuroborreliosis central nervous system injury, but that "the authors seem to dismiss, as speculation, molecular mimicry because 'T-cell lines demonstrate only weak cross-reactivity between myelin basic protein and B burgdor[f]eri.'" Id. at *57 (quoting Pet'r's Ex. 42 at 1083). The special master then remarked that in the Ramesh article, the authors demonstrated that infection with the B. burgdorferi spirochete "leads to inflammation and inflammation can be harmful," but noted that they did not use the term "autoimmunity" and that Dr. Venkatesan "persuasively explained[] the presence of immune cells does not necessarily mean that an injury's etiology is autoimmune." Id. Finally, the special master highlighted Dr.

Tornatore's recognition that "researchers are considering multiple mechanisms, not just autoimmunity, as ways to explain how neuroborreliosis develops." Id. After assessing the relevant body of evidence, the special master determined that petitioner did not establish "that neuroborreliosis is an autoimmune condition." Id. at *58.

Petitioner complains that the special master "rejected" each article relied upon by Dr. Tornatore, Mot. 12, and asserts that the articles support the proposition that neuroborreliosis is an autoimmune disease. Petitioner also identifies another piece of supportive evidence that she claims is significant (without actually contending that the special master disregards it): that Dr. Tornatore posited in one of his expert reports "that even after the [B. burgdorferi] infection ha[s] been treated with antibiotics, ongoing injury to the nervous system may occur as a result of the immune cascade that was triggered." Id. However, it is apparent from the special master's analysis that he considered the evidence offered in support of the proposition that neuroborreliosis is an autoimmune demyelinating disease—including Dr. Tornatore's theory concerning the immune cascade, see Hodge, 2023 WL 4186513, at *57 n.70—and found it insufficient for petitioner to satisfy her burden. Consequently, petitioner's contention that the special master legally erred in his analysis of the first inquiry under Loving prong 4 is not well-founded.[10]

Because the theory of causation advanced by Dr. Tornatore was premised on neuroborreliosis being an autoimmune demyelinating disease, petitioner's failure to satisfy her burden of proof on that element necessarily means that she cannot prevail on her claim that the hepatitis B vaccinations significantly aggravated Mr. Hodge's neuroborreliosis. Moreover, this failure renders petitioner's criticism of the special master's analysis of the second inquiry, which focuses on whether a hepatitis B vaccination can cause or aggravate an autoimmune demyelinating disease, moot. Nevertheless, for the sake of completeness, the court will address it.

To assess petitioner's contention that the hepatitis B vaccination can, in fact, cause or aggravate an autoimmune demyelinating disease, the special master reviewed the entire record before him, but concentrated on the evidence that petitioner identified as being the most supportive of her contention. He began by describing Dr. Tornatore's opinion that the hepatitis B vaccination could cause autoimmune demyelination via molecular mimicry, and then analyzed the five articles that Dr. Tornatore relied upon in forming his opinion. Petitioner addresses four of these articles in her motion for review: the Matsui, Bogdanos, Comenge and Girard, and Waisbren articles.

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[10] Petitioner, in a footnote, also lodges an extensive objection to the special master's statement that "Dr. Venkatesan has a stronger background in Lyme disease because he works at a center for studying Lyme disease." Hodge, 2023 WL 4186513, at *57, quoted in Mot. 12 n.13. The court reiterates that it need not entertain arguments raised in footnotes, see SmithKline Beecham, 439 F.3d at 1320, but observes that a special master's findings as to the credibility of an expert's testimony are entitled to a high degree of deference, see Porter v. Sec'y of HHS, 663 F.3d 1242, 1250-51 (Fed. Cir. 2011) (summarizing precedent indicating that such credibility determinations are virtually unreviewable).

First, with respect to the Matsui article, the special master noted that the authors described the experiences of a patient diagnosed with recurring episodes of demyelinating transverse myelitis who carried hepatitis B surface antigens and myelin basic protein in his cerebrospinal fluid, and postulated that "the persistence of [hepatitis B virus] components including [hepatitis B surface] antigen in the [cerebrospinal fluid]/[central nervous system] of the patient may contribute to the recurrent demyelinating lesion formation in the [central nervous system]." Id. at *61 (quoting Pet'r's Ex. 51 at 237). The special master discounted this article because it was a case report regarding a single individual, and noted another shortcoming: there is no indication that the patient at issue received a hepatitis B vaccination.

The special master next described the contents of the Bogdanos article. The authors searched for amino acid "similarities between the small hepatitis B virus surface antigen (SHBsAg), and the [multiple sclerosis]-autoantigens myelin basic protein (MBP) and myelin oligodendrocyte glycoprotein (MOG) that could serve as targets of immunological cross-reactivity." Id. (quoting Pet'r's Ex. 48 at 217). They found that 60% of serum samples from individuals vaccinated against hepatitis B "had SHBsAg/MOG double reactivity on at least [one] occasion," id. (quoting Pet'r's Ex. 48 at 217), but as the special master observed, they did not draw a definitive conclusion: "In view of the observed SHBsAg/MOG cross-reactivity, the vaccine's possible role as a trigger for the induction and/or maintenance of viral/self cross-reactivity through molecular mimicry must be further investigated." Id. at *62 (quoting Pet'r's Ex. 48 at 223). Indeed, as recognized by the special master and acknowledged by Dr. Tornatore, the authors reported that none of the vaccinated individuals "reported symptoms of demyelinating disorders," id. (quoting Pet'r's Ex. 48 at 222); accord id. ("All of the vaccinees were free of autoimmune phenomena before vaccination and remain free of any adverse reactions during the follow up." (quoting Pet'r's Ex. 48 at 222-23)).

The final two articles addressed by petitioner—the Comenge and Girard article and the Waisbren article—were published in 2006 and 2008 in a journal titled Medical Hypotheses. The special master explained that the authors of the first article "appear to summarize some research that, in their view, supports their hypothesis that the 'hepatitis B vaccine . . . has a marked potential to induce auto-immune hazards, neurological as well as non-neurological,'" due to a hypothesized effect of the vaccine manufacturing process, and "end by suggesting that the potential benefits of vaccination against hepatitis B be reevaluated." Id. (quoting Pet'r's Ex. 50 at 84). He then explains that the author of the second article "appears to hypothesize that the hepatitis B vaccine when given to a person who already is infected with the Epstein-Barr virus may develop multiple sclerosis via molecular mimicry," and "proposes two experiments to test this hypothesis[.]" Id. Addressing both articles, the special master remarks that they presented hypotheses, not experimental data, and thus "it is difficult to deem either . . . article as meriting much evidentiary weight." Id.

The special master then addressed the articles as a whole. He observed that the most recent article was published in 2008, the Bogdanos and Waisbren articles suggested the need for further investigation, and another article (the Oldstone article published in 2005) characterized molecular mimicry as a hypothesis. The special master stated that he was not persuaded by Dr. Tornatore's explanation for the lack of subsequent investigations into whether the hepatitis B vaccine could cause an autoimmune demyelinating disease—that there would be no reason for

such investigations because "once it's been demonstrated, it's very hard to get something published if . . . there's data already out there," id. at *63 (quoting Hr'g Tr. 255)—because given the evidence in the record, it was "difficult to credit" Dr. Tornatore's "oral testimony that a causal link between the hepatitis B vaccine and demyelination has been 'demonstrated.'" id. Ultimately, he concluded:

> [T]he undersigned is mindful that petitioners do not have to prove any aspect of their cases with certainty. But, even at a lower level of proof, the evidence [petitioner] has produced does not meet her burden. She has not presented evidence of sufficient quantity and quality to show that the hepatitis B vaccine can aggravate a demyelinating condition.

Id.

Petitioner objects to the special master's analysis of the second inquiry. She explains why the Matsui, Bogdanos, Comenge and Girard, and Waisbren articles are supportive of her theory of causation notwithstanding the special master's criticisms. She further notes Dr. Tornatore's opinion that neuroborreliosis is similar to the demyelinating disease of multiple sclerosis and that another special master concluded in another case that the hepatitis B vaccination can cause multiple sclerosis. And, she emphasizes respondent's concessions that (1) neuroborreliosis symptoms can be aggravated by external triggers and (2) the basis of some autoimmune disease can be explained by molecular mimicry. Petitioner asserts that had the special master applied the correct burden of proof, he would have found that this evidence, when examined as a whole, amounts to preponderant proof that the hepatitis B vaccination can cause or aggravate an autoimmune demyelinating disease.

Petitioner's argument is not persuasive. The special master articulated the proper legal standard, reviewed the evidence in the record—including the evidence highlighted by petitioner in addition to the articles, see id. at *55-56, *57 n.70, *58 n.73—in light of that standard, and concluded, based on the totality of that evidence, that petitioner did not satisfy her burden of proof. In short, petitioner has not established that the special master's analysis of Loving prong 4 was not in accordance with law.[11]

D. Loving Prongs 5 and 6

Having concluded that the special master did not legally err in analyzing Loving prong 4, the court must deny petitioner's motion for review. Nevertheless, it will address petitioner's

[11] Petitioner does not contend that the special master's fact findings were arbitrary and capricious. Had she advanced such an argument, she would have found it difficult to prevail since that standard imposes a high bar: "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." Hines v. Sec'y of HHS, 940 F.2d 1518, 1528 (Fed. Cir. 1991); accord Lampe v. Sec'y of HHS, 219 F.3d 1357, 1360 (Fed. Cir. 2000) ("The arbitrary and capricious standard of review is difficult for an appellant to satisfy with respect to any issue . . . .").

additional, albeit abbreviated, challenges to the special master's conclusions under Loving prongs 5 and 6.[12]

With respect to Loving prong 5, petitioner objects that despite ruling that she had satisfied her burden of demonstrating the existence of a significant aggravation of Mr. Hodge's condition postvaccination under Loving prong 3, the special master concluded that "the evidence, viewed in its entirety, does not persuasively support that the hepatitis B vaccine significantly worsened an underlying neuroborreliosis manifesting as OCD." Mot. 18 (quoting Hodge, 2023 WL 4186513, at *64); see also Hodge, 2023 WL 4186513, at *82-83 (providing a "synopsis" of the special master's findings and conclusions under Loving prong 5). Specifically, petitioner complains that the special master "dismisses medical record evidence of neurological symptoms," including notations in April 25 and June 2, 2006 medical records; disregards neurological symptoms identified by Dr. Tornatore; and "rejects the evidence of several treating doctors." Mot. 18-19. However, a review of the special master's decision reflects that the special master carefully considered all of the evidence identified by petitioner in her motion, along with other evidence in the record, in determining whether she could satisfy her burden of proof under Loving prong 5. See Hodge, 2023 WL 4186513, at *64-83. In other words, petitioner has not established that the special master's analysis of Loving prong 5 was not in accordance with law.[13]

Petitioner's criticism of the special master's analysis of Loving prong 6 fares no better. In his decision, the special master observed that the "timing prong actually contains two parts," and that "[a] Petitioner must show the 'timeframe for which it is medically acceptable to infer causation' and [that] the onset of the disease (or aggravation) occurred in this period." Id. at *83 (quoting Shapiro v. Sec'y of HHS, 101 Fed. Cl. 532, 542 (2011), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013)). He concluded that petitioner "established the first part of this element" and that had she "presented preponderant evidence that the uncontrollable eye movements" were "neurologic in origin," such "eye movements were noted within the time for which an inference of causation is appropriate." Id. In other words, petitioner would have established the second

[12] Petitioner devotes one paragraph to each prong in her motion for review. Mot. 18-19.

[13] Petitioner's complaint that the special master "dismisse[d]" or "reject[ed]" certain evidence might be construed as an argument that the special master improperly weighed the evidence in the record. Because petitioner did not explicitly raise such an argument, she has waived it. See SmithKline Beecham, 439 F.3d at 1319 ("[A]rguments not raised in the opening brief are waived."). Even if she did advance such an argument, she would have found it difficult to prevail because special masters "have very wide discretion" in determining what evidence to consider and "the weight to be assigned that evidence." Whitecotton v. Sec'y of HHS, 81 F.3d 1099, 1108 (Fed. Cir. 1996); accord Koehn v. Sec'y of HHS, 773 F.3d 1239, 1244 (Fed. Cir. 2014). Consequently, on review, the Court of Federal Claims does "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence." Porter, 663 F.3d at 1249; Hodges v. Sec'y of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993) (holding that "on review, the Court of Federal Claims is not to second guess the Special Master[']s fact-intensive conclusions"); Hines, 940 F.2d at 1527 ("[A]rguments as to the weighing of evidence . . . do not demonstrate reversible error.").

part of the timing prong if she had proven that Mr. Hodge's abnormal eye movements were a neurological symptom. The special master did not, as petitioner contends, conclude that petitioner "failed to prove the second component of Prong [6]," Mot. 19; rather, he concluded that her failure to satisfy her burden on Loving prong 5 rendered the second component of Loving prong 6 irrelevant. The court identifies no legal error in the special master's reasoning or conclusion.

III. CONCLUSION

In short, petitioner has not demonstrated that the special master required her to satisfy a heightened burden of proof to establish causation under the final three prongs of the Loving test. Rather, applying the proper legal standard to the record as a whole, the special master concluded that petitioner had not offered preponderant evidence that the hepatitis B vaccination can significantly aggravate neuroborreliosis, as required under Loving prong 4. Furthermore, contrary to petitioner's contention, the special master carefully reviewed the entirety of the record in determining that petitioner had not satisfied her burden of proof under Loving prong 5.

The court recognizes that petitioner and Mr. Hodge have suffered tremendously in the time since Mr. Hodge received his hepatitis B vaccinations, and that petitioner strongly believes that those vaccinations caused the significant deterioration of Mr. Hodge's condition. However, under the Vaccine Act, this court's review is limited. When the sole objection presented is that the special master applied the wrong legal standard and therefore acted contrary to law, the court's inquiry necessarily ends if it concludes that the special master applied the correct legal standard. Such is the case here.

Accordingly, the court **DENIES** petitioner's motion for review and **SUSTAINS** the decision of the special master. The clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Margaret M. Sweeney
MARGARET M. SWEENEY
Senior Judge